PMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P-0086]

Determination That Sutilains Ointment USP Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that sutilains ointment USP (Travase® Ointment) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for sutilains ointment USP.

FOR FURTHER INFORMATION CONTACT: Andrea C. Masciale, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301-594-5648.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products with Therapeutic Equivalence Evaluations, " which is generally known as the "Orange Book. " Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314. 162). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On February 11, 1998, Hogan & Hartson, L.L.P. submitted a citizen petition (Docket No. 98 P–0086/CP1) under 21 CFR 10.30 to FDA requesting that the agent y determine whether sutilains ointment USP was withdrawn from sale for reasons of safety or effectiveness. Sutilains ointment USP (Travase® Ointment) is the subject of NDA 12-828. FDA approved NDA 12–828, held by Travenol Laboratories, on June 12, 1969. The right to market sutilains ointment USP was subsequently transferred to Boots Pharmaceuticals, Inc., which became part of Knoll Pharmaceuticals (Knoll) on April 1, 1995. Knoll stopped distribution of the drug product effective March 29, 1996.

FDA has reviewed its records and, under § 314.161, has determined that Knoll's decision not to market sutilains ointment USP was not for reasons of safety or effectiveness. Accordingly, the agency will move sutilains ointment USP to the "Discontinued Drug Product List" section of

the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to sutilains ointment USP may be approved by the agency.

Dated: October 9, 1998

William K. Hubbard
Associate Commissioner for Policy Coordination

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